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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,200	02/06/2001	John Kisiday	01997/537001	8784

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/118200

Applicant(s)

Kis. Day Inf

Examiner

N. P. D.

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/6/03
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above claim(s) 9-18 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 (file 2/14/01)
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

In a response of 1/6/03 to a restriction requirement of 7/1/02, applicants elected Group I claims 1-8 without traverse.

Claims 9-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no
5 allowable generic or linking claim. Election was made without traverse in Paper No. 11 of 1/6/03.

Claims examined on the merits are 1-8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

10 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as
15 being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are confusing and unclear by claim 1 being unclear as to the relationship of the peptides to the scaffold and the cells. It is unclear as to whether the peptides are only a component of the scaffold
20 or whether the scaffold is formed by the peptides self-assembling into a beta-sheet macroscopic scaffold that encapsulates the cells.

In claim 2, "chemoattractant" is uncertain as to meaning and scope. This does not appear to be an term having an art recognized meaning.

In claim 7, "equilibrium compression modulus" is uncertain as to
25 meaning and scope. If this term has an art recognized meaning in the text of the claim, evidence should be provided.

Claim 8 is confusing by requiring at least 60% of the encapsulated cells to be in cell-cell contact with another encapsulated cell or another cell outside the scaffold without setting forth conditions that result in the contact with another encapsulated cell or cell outside the scaffold.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15 Claims 1, 3, 5, 6 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Kisiday et al (A New Self-Assembling Peptide Gel-----) (abstract, International Cartilage Repair Society) (PTO-1449).

The claims are drawn to a macroscopic scaffold encapsulating living cells and containing amphiphilic peptides that self-assembled into a beta-sheet.

Kisiday et al disclose a self-assembling peptide gel matrix encapsulating chondrocytes that is the same the presently claimed scaffold. The chondrocytes would have inherently secreted an extracellular matrix as required by claim 6, and would have inherently increased equilibrium compression modulus as required by claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not
15 commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kisiday et al in view of Hubbell (6,129,761) .

20 The claim requires the scaffold to contain a therapeutically active compound or chemoattractant.

Hubbell discloses a scaffold for implanting containing cells encapsulated in a hydrogel (col 5, lines 55-60) which can contain biologically active agents such as therapeutic agents (col 7, lines 15-
25 21) .

It would have been obvious to include a therapeutic agent in the gel matrix of Kisiday et al to obtain the known therapeutic function of the agent as suggested by Hubbell. It would have been obvious to implant the scaffold of Kisiday et al as suggested by Hubbell, and

when implanted, cell-cell contact with cells outside the scaffold as required by claim 8 would have been inherent.

Claim Rejections - 35 USC § 103

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable
5 over Kisiday et al in view of Holmes et al (PNAS) (PTO-1449).

The claim requires the cells to be neurons.

Holmes et al disclose attaching neurons to a self-assembling peptide scaffold and growing the neurons.

It when have been obvious to use neurons as the cells of Kisiday et
10 al when the function of neurons is desired as suggested by Holmes et al attaching neurons to a self-assembling peptide scaffold.

Claim Rejections - 35 USC § 103

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes et al (5,955,343) or Zhang et al (Biomaterial
15 1995) (PTO)-1449) in view of Hubbell (6,129,761), and if necessary in further view of Kisiday et al (applied above).

The invention and references except for Holmes et al and Zhang et al are described above.

Holmes et al (col 11, lines 32-35) and Zhang et al disclose
20 culturing cells on a membrane of matrix formed by self-assemble of peptides as presently claimed.

Rather than culture the cells on the membrane of Holmes et al or the matrix of Zhang et al, it would have been obvious to encapsulate the cells in the membrane or matrix as suggested by Hubbell encapsulating

cells in a hydrogel for implanting, and if needed as further suggested by Kisiday et al encapsulating cells in a self-assembling peptide gel.

Claim Rejections - 35 USC § 103

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable
5 over the references as applied to claims 1-3 and 5-8 above, and further in view of Holmes et al (PNAS).

When encapsulating cells in a self-assembling peptide membrane or matrix as set forth above, it would have been obvious to use neurons as the cells to obtain the function of neurons as suggested by Holmes et al
10 (PNAS) attaching neurons to a self-assembling peptide scaffold.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00
15 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
20 (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
4/7/03 .